

Summary of Public Comments
Department of Health and Human Services, 10-144, Chapter 275, Section 2
Reporting of Prescription Drug Marketing Costs

The Department of Health and Human Services held a public hearing on May 15, 2006 to propose rules relating to the Reporting of Prescription Drug Marketing Costs. Comments were accepted at the public hearing and by mail and electronically through June 1, 2006. Following is a summary of the public comments and the Department's responses. A Table of Commenters appears at the end of this document.

Section 2.01 – Statutory Authority and Purpose

1. **Comment:** The commenter suggests that section 2.01 expressly state that the rules do not apply to products that meet the definition of medical devices under U.S. federal law, and suggests clarifying the scope of the rules to indicate their application only to FDA-approved prescription drugs and biologics. (1)

Response: The Department has clarified that the rules apply to any product dispensed with a prescription and covered by a State of Maine pharmacy benefit.

Section 2.02 - Definitions

2. **Comment:** The commenter suggests that 25% ownership is not enough to have a controlling interest over the management and policies of the corporation. The commenter further suggests, instead of the 25% ownership test for affiliate, that the Department adopt the "50% ownership test" consistent with the Maine Biomedical Research Program definition of affiliate, pursuant to 5 M.R.S.A §13103(1)(A-2). (5)

Response: In response to this comment, the Department has adopted as one standard the 50% ownership test.

3. **Comment:** The commenter feels the 25% ownership threshold may not adequately address the range of business relationships the law seeks to capture, and suggests that multiple donations by one or many pharmaceutical companies (e.g., to medical education companies) could create a loophole in reporting. (8)

Response: The Department believes that significant marketing through a collaboration of more than one manufacturer occurs rarely but will reconsider this issue in the future. The Department has clarified that payments to medical education companies constitute reportable marketing expenses.

4. **Comment:** The commenter suggests that information provided by a labeler or manufacturer in response to an unsolicited request for disease or research information be excluded from the definition of marketing. (1)

Response: The Department has concluded that such a distinction cannot be maintained and has made no changes to the final rules as a result of this comment.

5. **Comment:** The commenter recommends that “marketing” be defined more clearly and insists that some of the examples (e.g., CME and charitable grants) would not generally be interpreted as marketing or be regulated by Federal law as marketing. The commenter recommends that the Department use standards available under the Federal Food, Drug, and Cosmetic Act (FFDCA) in crafting its definition of marketing. The commenter further recommends that, instead of providing a definition of marketing, the rules provide a list of examples of what would be considered marketing under the statute. (6)

Response: The Department does not agree that the purpose of the Maine statute is served by narrowly defining marketing. The Department believes that providing examples of marketing may be the most helpful method of clarifying the definition. The Department made no changes to the final rules as a result of this comment.

Section 2.03 – Reporting – General Requirements

6. **Comment:** The commenter suggests clarifying that the reporting of 2006 data is not required in 2006, but rather 2006 data should be reported in the 2007 annual report. The commenter further suggests that the first two quarters of 2006 be excluded given that the final rules will not be effective during this time. (1)

Response: The commenter is correct that the reporting of 2006 data is not required until July 2007. As it states under this section of the rule, initial reports are due “by July 1 of each year as of July 1, 2007.” Also as provided in the rules, in the report due July 1, 2007, manufacturers may substitute an explanation in lieu of data for a portion of the 2006 data. In response to this comment, the Department has clarified the language in the rule.

7. **Comment:** The commenter believes that it would be unreasonable to require any reporting for 2006 since the Department did not even propose the rules until April 2006. Forgoing the 2006 reports would allow manufacturers time to develop the necessary data capture and reporting systems. At a minimum, the commenter recommends that the Department not impose penalties for failure to report marketing information for 2006. (5)

Response: The Department has revised the rules to permit manufacturers to substitute an explanation in lieu of data for the first three quarters of 2006. While the Department does not agree that it is unreasonable to expect manufacturers to begin reporting for the final quarter of 2006, the Department is aware of the challenges posed by the timing of these rules.

Section 2.04 – Content of Annual Report by manufacturer or Labeler

8. **Comment:** The commenters recommend that the reporting of “all expenses” include only expenses related to activities that occur in Maine or are directed towards residents of Maine or providers licensed and practicing in Maine, and should expressly exclude national and regional activities that do not meet these requirements (1, 7). One commenter adds that payments to Maine health care providers that are “not reasonably characterized as marketing or promotional expenses,” such as research, consulting or clinical trial activities should also be excluded. (1)

Response: The Department has clarified this section of the rules. A list of exceptions provided in section 2.05 of the rules already excludes reasonable compensation and reimbursement for expenses in connection with a bona fide clinical trial.

Section 2.04-1

9. **Comment:** The commenter states that the phrase “as they pertain to” is vague and unclear and should be changed to “made to.” (1)

Response: The Department agrees and has revised the language.

Section 2.04-2(A)

10. **Comment:** The commenter recommends identifying the types of expenses sought with greater specificity, and to exclude normal operating expenses not directly associated with education or information programs or materials. (1)

Response: The Department has clarified that expenses not directly associated with educational or information programs are excluded.

11. **Comment:** The commenters suggest deleting the requirement to report expenses relating to continuing medical education because they are not properly considered marketing or promotional activities, and that such a requirement is “probably reaching beyond statutory authority.” (1, 6) One of the commenters recommends clarifying that manufacturer or labeler contributions to national professional associations for member conferences/meetings not held in Maine be excluded from reporting. (1)

Response: The Department disagrees that continuing medical education is outside the scope of the statutory requirement to report expenses. The intention of the statute and rules is to capture expenses of marketing and promotional activities that are directed toward Maine providers, regardless of location. The Department has added clarifying language.

12. **Comment:** The commenters believe that “support for continuing medical education programs” does not fall within the scope of 22 M.R.S.A. §2698-A, is contrary to industry standards, and that independent and accredited educational programs should be exempted from this provision. (5, 7)

Response: See the response to the previous comment.

13. **Comment:** The commenter recommends that the requirement to report expenses associated with disease management materials be reportable only when they are designed specifically for health plans located in Maine, and only if the name of the manufacturer appears on the materials and they contain a significant discussion of an approved prescription drug. (5)

Response: The Department agrees in part and has clarified with additional language. The Department agrees that expenses for disease management materials designed specifically for Maine users are reportable in whole. However, the printing costs of those materials distributed in Maine are reportable regardless of for whom/what/where they were designed. The Department also brought this requirement into conformity with the Maine statute by not limiting reporting to materials upon which the name of the manufacturer appears.

14. **Comment:** The commenter suggests deletion of “consulting activities” from this section of the rules, or to at least clarify and limit the scope of consulting activities given that the statute is limited to prescription drug marketing costs. The commenter suggests the following language: Consulting activities relating to the marketing of new or unapproved (“off label”) uses of approved drugs. (1)

Response: The reference to reporting new or unapproved drugs was intended as an example, not a limitation. Because of the potential for payments to influence health care professionals in ways that may affect the sales of drugs, the Department intends the rule to capture the payment of consulting fees to health care professionals except as connected to bona fide clinical trials. However, the Department has clarified the reporting requirement in the list of examples. The Department has also defined “bona fide clinical trial.”

15. **Comment:** The commenter feels that restricting the disclosure of consulting fees to apply only to “unapproved drugs or off-label uses” of drugs is too narrow and recommends revising the bullet to require disclosure of “any consulting fees, or any other payments or grants” to a physician or other prescriber. (2, 8)

Response: The Department agrees and intended its reference only as an example. See the response to the immediately prior comment.

16. **Comment:** The commenter suggests adding a bullet or bullets that would require disclosure of: a) payments for participation in speakers’ bureaus; and b) honoraria or other payments for time while speaking at or attending meetings, lectures or conferences. (2)

Response: The Department agrees and has added these activities to the list. The Department did not intend for this to be an exhaustive list.

17. **Comment:** The commenters believe that the requirement to report bona fide “consulting” expenses exceeds statutory authority and should be deleted (5, 7). Commenter 5 suggests that the reference to “activities supporting use of unapproved drugs or new (off label) uses of approved drugs” is vague and urges the Department to clarify which expenses would fall into this category.

Response: The Department disagrees that its rules exceed statutory authority but has attempted to clarify the scope of the rules.

18. **Comment:** The commenter requests the Department to clarify what is meant by “new” and “off label” uses. The commenter further insists that federal law prohibits manufacturers from marketing an unapproved drug or an off label use of an approved drug and, hence, the proposed rules are essentially asking manufacturers to report costs of an illegal activity. (6)

Response: The Department has deleted this example but notes that consulting fees and expenses remain reportable under the rules.

19. **Comment:** The commenter believes that the inclusion of consulting or “supporting” activities conflicts with Section 2.05 of the proposed rule, which exempts expenses associated with “a bona fide clinical trial of a new vaccine, therapy, treatment, or indication.” (6)

Response: Section 2.05 contains a list of exceptions that are applicable and valid, notwithstanding broad language elsewhere in the rules. The Department has also clarified the requirement to report consulting fees.

20. **Comment:** The commenters recommend deleting the requirement to report charitable grants since they are not marketing expenses for prescription drugs and is beyond the scope of the statute. (1, 5, 6, 8) Commenter 6 refers to the Guidance for Pharmaceutical Companies developed by the Office of the Inspector General (“OIG Guidance”) and argues that, “grants cannot reasonably be considered to be marketing activities and should be excluded from the list of examples of such activities.” Alternatively, Commenter 1 suggests clarifying this provision with the following revision: Charitable grants, even if unrestricted, to Maine providers or educational, professional or nonprofit institutions formed under Maine law and operating in Maine for the purpose of marketing prescription drugs in the State.

Response: The Department disagrees that charitable grants are beyond the scope of the statute because they often serve promotional purposes. However, the Department has clarified the requirement through this section and through section 2.04-1.

21. **Comment:** With respect to patient education materials, the commenter recommends limiting this requirement to printing costs and feels the proposed language is too broad and could be interpreted to include the payroll, personnel, and overhead costs of the persons who draft, review, and distribute branded patient education materials. (1)

Response: The Department has limited this requirement to report expenses associated with patient education materials to printing costs, unless designed specifically for use in Maine.

22. **Comment:** The commenters recommend that expenses associated with patient education materials be reportable only if the name of the manufacturer appears on the materials and they contain a significant discussion of an approved prescription drug. (5, 6)

Response: The Department disagrees and instead believes it is more consistent with the statute to require the reporting of the printing costs of all patient education materials distributed in the Maine market, regardless of identification of the manufacturer or discussion of an approved prescription drug.

23. **Comment:** The commenter suggests clarifying what is meant by “market research surveys” and “other activities undertaken in support of developing advertising and/or marketing strategies.” As presently drafted, the commenter believes the rule could be interpreted to include the direct and indirect personnel and overhead costs, including payroll, of most persons in a company. The commenter suggests narrowing the scope to cover only those recipient types identified in Appendix A. (1)

Response: The Department has clarified the language under this section to indicate that only payments directly or indirectly made to a person or entity licensed to provide health care in Maine are reportable.

24. **Comment:** The commenters suggest that market research surveys are not commonly considered marketing or advertising, and furthermore that many of the surveys performed by outside vendors remain “blinded” to the manufacturer and, consequently, should be excluded. The commenters also express concern about the difficulty drug manufacturers would have in

allocating to Maine the expenses of any survey that did not involve a health care professional within Maine. (5, 6) Commenter 6 suggests excluding the costs of surveys that follow the standards promulgated by the Council of American Research Survey Organizations provided as Exhibit A.

Response: The Department disagrees that all market research survey expenses should be excluded but has clarified that the requirement is limited to payments that go to persons or entities licensed to provide health care in Maine.

Section 2.04-2(B)

25. **Comment:** The commenter suggests adding the language “per interaction” after stating the \$25 threshold to be consistent with Section 2.05. (1)

Response: In response to this comment, the Department has amended the language so that it applies to expenses per day, which is more definable than per interaction.

26. **Comment:** The commenter disagrees with the Department’s example (attributing the “in-whole” expense of a \$60 luncheon for three physicians) as being reportable under this section. The commenter states that the standard industry practice is to pro-rate the total cost of such a luncheon among the health care professionals involved. Thus, in the example given, the expense associated with each physician would be only \$20 and not reportable. The commenter recommends deletion of this example. (5)

Response: The Department disagrees that the costs should be prorated when the gift of food is to persons of the same office and made no changes to the final rules as a result of this comment.

Section 2.04-2(C)

27. **Comment:** The commenters recommend that this language be entirely struck because current federal law prohibits payments to prescribers to induce referral of business. (1, 5)

Response: The Department believes that payments made to health care professionals for trips and travel can be marketing in effect. The Department made no changes to the final rules as a result of this comment.

28. **Comment:** The commenter states that the requirement to report “expenses associated with trips and travel” lacks clarity as to its scope and further suggests that these are not “marketing” expenses and thus would not be reportable under 2698-A(4). The commenter requests that the Department specify which, if any, trips and travel expenses are in fact reportable. (5)

Response: In response to this comment, the Department has revised language to require the reporting of only the costs of trips and travel. The Department believes that it has the statutory authority to require the reporting of these expenses because they can be marketing in effect.

Section 2.04-2(D)

29. **Comment:** The commenter recommends clarifying the types of samples and starter kits that need to be reported since nearly all of these products are intended for distribution free of charge to patients. (1)

Response: The Department believes the commenter may be correct that most samples and starter kits need not be reported. No change was made as a result of this comment.

Section 2.04-3

30. **Comment:** The commenters suggest revising this section to permit allocation of expenses relating to regional or multi-state marketing employees or contractors by methods other than the sole method provided, and that only those expenses related to activities that occur in Maine or directed to Maine-licensed prescribers who are practicing in Maine should be reportable. (1, 7)

Response: The Department agrees that reporting under this section is limited to activities directed to Maine. In response to this comment, the Department has revised the rule to permit an allocation of expenses in proportion to Maine for those persons whose activities occur in two or more but fewer than six states.

31. **Comment:** The commenters suggest requiring disclosure of drug manufacturers' payments to medical education communication companies (MECCs) that conduct educational or informational programs, materials and seminars for medical providers. (2, 8)

Response: The Department has clarified language to reflect the Department's intent to include this requirement.

32. **Comment:** The commenters recommend clarifying the language in the proposed rule to be consistent with the statutory language cited in 22 M.R.S.A. §2698-A(4) (i.e., "as it pertains to marketing activities conducted within this State"), and to properly reflect the exclusion of "expenses associated with advertising purchased for a regional or national market that includes advertising within the State." (5, 6)

Response: In response to this comment, the Department has clarified language to reflect the Department's intent as to the scope of this provision.

33. **Comment:** The commenters state that there is no language in the statute to support the 50% threshold for "time spent on marketing" and are therefore opposed to this limitation. (2, 8)

Response: The Department agrees that the threshold is not referenced in the statute. In response to this comment, the Department has modified this requirement to require reporting of the information most directly relevant to the statute, i.e., the compensation of persons engaged in the marketing activities and not the costs of administrative or incidental support.

34. **Comment:** The commenter suggests that personnel who provide administrative support or supervision are not engaged (directly or indirectly) in advertising or promotional activities and suggests eliminating the requirement to report costs associated with administrative support or supervision. (5)

Response: In response to this comment, the Department agrees insofar as the personnel are involved only in administrative or incidental support or indirect supervision and has amended the language to reflect this.

35. **Comment:** The commenters recommend that the 50% rule be limited to personnel who spend more than 50% of their time supporting or supervising marketing and/or promotional activities that occur in Maine, and request that the proposed rules clarify that national, regional and international employees are not reportable. (5, 6)

Response: The Department disagrees and did not make that change in the language. The Department has eliminated the 50 percent threshold.

36. **Comment:** The commenter recommends that manufacturers, when providing services to six (6) or more states, be allowed to allocate costs in the manner provided (i.e., by dividing by the number of states served) *any time* an employee or contractor serves more than one state and data specific to Maine are not reasonably available. (5) Similarly, another commenter suggests changing the “six-state” rule to a “two-state” rule to be applied whenever two or more states are served. (6)

Response: The Department disagrees but in response to this comment has clarified that the reported cost may be based on an estimate of the proportion of effort toward Maine when an employee or contractor provides services to two but fewer than six states and data is not available.

37. **Comment:** The commenter has concerns that the six-state rule could be interpreted in such a way so as to include non-marketing costs and suggests clarification of this section of rules. An example is provided. (6)

Response: The Department has clarified this section.

38. **Comment:** The commenter expresses concerns regarding the inclusion of employee/contractor “overhead” costs under this section and struggles to conceive of a formula for allocating such costs on a per-employee, per-state or per-prescription-drug basis. The commenter feels that the rules as drafted will create a burden that is extreme enough that covered entities will divert their resources away from the State of Maine, and thus jeopardize the provision of patient and provider education in Maine, as well as patient samples. Alternate draft language is offered for the entire section. (6)

Response: In response to this comment, the Department has deleted this portion of the reporting requirement.

Section 2.04-4

39. **Comment:** Instead of asking the company to provide the name and contact information annually in October, the commenter suggests the rules be modified to ask that contact information be supplied with the annual report in July and that companies only need to update this information in later years if the contact person changes. (6)

Response: In response to this comment, the Department has changed the time frame by which manufacturers are required to report the company contact information so as to align it with the annual report that is due by July 1 of each year, beginning July 1, 2007. This information is to be reported annually. However, the Department does not agree that it would be sufficient to merely update contact information if the contact person changes.

Section 2.05 - Exceptions

40. **Comment:** The commenter suggests the following language to clarify the first two bullets under this section:

The following ~~marketing~~ expenses are not subject to the requirements of this section:

- Marketing ~~E~~xpenses of twenty-five dollars (\$25) or less per health care professional;
- Reasonable compensation and reimbursement for expenses in connection with a bona fide clinical trial of a new vaccine, therapy, treatment, or indication; ~~and whether or not~~ considered or meeting the definition of a “covered clinical trial” or a “clinical trial conducted or sponsored” by a manufacturer or labeler or prescription drugs or biologics; and

The commenter believes that bona fide clinical trial expenses are not prescription drug marketing costs and thus should be excluded. (1)

Response: In response to this comment, the Department has adopted some clarifying language. The Department agrees that expenses in connection with a bona fide clinical trial are excluded from reporting.

41. **Comment:** The commenter expresses concern that the rules do not define “bona fide clinical trial” which creates a loophole for trials and surveillance studies that masquerade as research, but in reality are marketing campaigns. (8)

Response: In response to this comment, the Department has included a definition of “bona fide clinical trial” in the final version of the rules.

Section 2.06-1 - Department Report

42. **Comment:** The commenter suggests revising this section to ensure that sensitive information cannot inadvertently be made public while reporting under this section, and recommends cross-referencing section 2.07-1 to affirm that trade secret information is not a public record. (1)

Response: The Department believes the proposed rules contain adequate safeguards to protect trade secret information and made no changes to the final rules as a result of this comment.

43. **Comment:** The commenter expresses appreciation for the Department’s efforts to respect the industry’s concerns regarding confidentiality of proprietary information and offers to work with the Department when it prepares its reports. The commenter also requests that the proposed rules make clear that manufacturers may submit their data electronically, in a major spreadsheet or database format. (5)

Response: The Department appreciates the commenter’s willingness to collaborate on this initiative. While the exact reporting format has yet to be determined, the Department will provide this information after adoption of these rules.

44. **Comment:** The commenter suggests that the Department work with covered entities in developing a format to ensure that no trade secrets are revealed, and believes that the

presentation of aggregate data should not be broken out by company or identify any company by name but should instead provide industry-wide numbers. (6)

Response: The rules state that the information shall be provided in aggregate form. The Department believes the proposed rules contain adequate safeguards to protect trade secret information and made no changes to the final rules as a result of this comment.

Section 2.07-1 – Confidentiality, Public Information

45. **Comment:** The commenter suggests adding a statement to affirm that information submitted to the Department or Attorney General pursuant to 22 MRSA § 2698-A is, in addition to being considered confidential, also non-disclosable as a trade secret or other form of proprietary information under state law. (1)

Response: Maine statute already defines trade secrets. The Department believes the proposed rules contain adequate safeguards to protect confidentiality and trade secret information and made no changes to the final rules as a result of this comment.

Section 2.08 - Penalty

46. **Comment:** The commenter suggests including more specific enforcement and penalty language to deter delayed, incomplete or other evasive reporting practices, and that each infraction will constitute a separate violation. (8)

Response: In response to this comment, the Department clarified the requirement to file a timely, complete and accurate report while mirroring the statutory language.

Appendix A – Specific Reporting Requirements

47. **Comment:** The commenter suggests revising Appendix A to: a) state that all information provided is trade secret and confidential per sections 2.06-1 and 2.07-1; b) allow for electronic submission of information along with pre-populated (including “Other”) and blank drop down boxes to allow for description of credentials and primary purpose; and c) delete “secondary purpose of payment, if applicable.” (1)

Response: Respectively: a) the Department believes the proposed rules contain adequate safeguards to protect confidentiality and trade secret information and made no changes to the final rules as a result of this comment; b) while the exact reporting format has yet to be determined, the Department will provide this information after these rules are made final; and c) the Department has deleted the requirement to report “secondary purpose of payment.”

48. **Comment:** The commenter suggests revising Appendix A to: a) request approximate dates of activity or a range of dates for an advertising or similar activity; and b) exclude information that is provided to a person in Maine in response to that person’s unsolicited request. (1)

Response: Respectively: a) while the exact reporting format has yet to be determined, the Department will provide this information after the rules are made final; and b) the Department has concluded that a proper distinction is not possible in this regard and made no changes to the final rules as a result of this comment.

49. **Comment:** The commenter feels the reference to both a “primary purpose” and “secondary purpose” is confusing and suggests calling it “purpose” (or “purposes”) to simplify this item. (5)
- Response:** The Department agrees and has deleted the requirement to report “secondary purpose of payment.”
50. **Comment:** The commenter believes the Department’s use of the word “gift” (in the first line of the Appendix) does not accurately describe the items contained therein (e.g., consulting fees, charitable grants and speaker fees). The commenter recommends that the first section of Appendix A address only items reportable under proposed 2.04-2(B) (i.e., expenses associated with food, entertainment, gifts), and the second section of Appendix A address all other expenses reportable under the new rules. (5)
- Response:** In response to this comment, the Department has amended the opening line of this section to require reporting of “each gift/payment that meets the requirements for mandated reporting.” The basic format of Appendix A remains unchanged.
51. **Comment:** With respect to the requirement to report the “credentials” of each recipient, the commenter states this information is not always readily available and suggests eliminating it from the reporting template. (5)
- Response:** The Department disagrees and believes that this information will be useful to the Department. The Department has not changed the final rules as a result of this comment.
52. **Comment:** The commenter recommends that the Department allow manufacturers to use a commercially available spreadsheet or database program for submission of the required reports. (5)
- Response:** While the exact reporting format has yet to be determined, the Department will provide this information after the rules are made final.

Comments Not Specific to Sections of the Proposed Rule

53. **Comment:** The commenter suggests that the proposed rules appear to exceed the “jurisdictional scope” of the statute (22 M.R.S.A. §2698-A), which more clearly points to the reporting of Maine-specific marketing costs. The commenter feels that this jurisdictional limitation should be better reflected in the rules. (6)
- Response:** In response to this comment, the Department has attempted to clarify the scope of the rules.
54. **Comment:** The commenter feels that the rules do not provide any procedural safeguards to adequately protect trade secret information and requests a procedure by which covered entities would receive “reasonable advance written notice” of any requests for the aggregate data with an opportunity to comment on the format and content of the requested data. The commenter offers draft language. (6)
- Response:** The Department believes the proposed rules contain adequate safeguards to protect trade secret information and made no changes to the final rules as a result of this comment.

55. **Comment:** Due to the potential difficulties covered entities may have in reporting to the Department, the commenter requests that the rules include a “best-efforts certification” to protect manufacturers who will be unable to provide some of the information due to organizational, regulatory and other barriers. The commenter offers draft language. (6)

Response: The Department is unwilling to rely on a best-efforts standard but has attempted to require the reporting only of information that is obtainable or collectable. The Department made no changes to the final rules as a result of this comment.

56. **Comment:** The commenter believes that all data under the statute should be provided in an aggregate form and sees no need to report company-specific “disaggregated” data. This would also ensure greater protection with respect to confidentiality and trade secret information. (7)

Response: The Department disagrees that the data will be as meaningful in an aggregate form. The Department made no changes to the final rules as a result of this comment.

57. **Comment:** The commenter states that gifts and marketing activities are often difficult to identify, and the scope and remuneration to physicians are not always straightforward. The commenter urges the Department to broadly define the information to be collected so that de facto marketing costs and all types of gifts, such as free or in-kind services, payments to physicians as “consultants” in name only, and ghostwritten articles will be properly disclosed. (8)

Response: In response to this comment, the Department has elaborated upon information that is required to be reported under section 2.04-2 of the rules and has clarified that expenses for free and in-kind services must be reported.

Finding of Fact:

The Office of the Attorney General, after review of the proposed rule, Chapter 275, Section 2, Reporting of Prescription Drug Marketing Costs, has advised the Department of Health and Human Services, to amend the proposed rule to clarify the meaning of the term, “Significant educational, scientific or policy-making conference or seminar,” contained in both §2.05 of the rule and Paragraph 5 of the enabling statute, 22 M.R.S.A. §2699-A.

Accordingly, the Department has amended Section 2.02 of the proposed rule to include a definition of the term. The term has been defined to mean an educational, scientific or policy-making conference or seminar that offers continuing medical education credit, features multiple presenters on scientific research, or is authorized by the sponsoring association to recommend or make policy.

Table of Commenters
10-144, Chapter 275, Section 2
Reporting of Prescription Drug Marketing Costs

1. Tom Dilenge, Biotechnology Industry Organization (Bio) (Genentech)
2. Earl Lui and Rob Schneider, Consumers Union
3. Justin P. McCarthy, Pfizer Inc.
4. Frazor Edmundson, Sepracor Inc.
5. Anne Robinson, PretiFlaherty for Marjorie Powell, Pharmaceutical Research and Manufacturers of America (PhRMA)
6. Beth A. Krewson, GlaxoSmithKline
7. Todd Kaufman, Genentech
8. Sharon Treat, National Legislative Association on Prescription Drug Prices (NLARx)
9. Donald O. Beers, Arnold and Porter LLP